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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/701,271	03/11/2002	Jean-Louis Ruelle	BM45323	8726

25308 7590 01/26/2004  
DECHERT  
ATTN: ALLEN BLOOM, ESQ  
4000 BELL ATLANTIC TOWER  
1717 ARCH STREET  
PHILADELPHIA, PA 19103

EXAMINER

BASKAR, PADMAVATHI

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 01/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/701,271

Applicant(s)

RUELLE ET AL.

Examiner

Padmavathi v Baskar

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 03 November 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 31, 36-39, 60-62, 65, 68, 69 and 71 is/are pending in the application.
- 4a) Of the above claim(s) 36, 37, 68 and 69 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 38 is/are allowed.
- 6) ☒ Claim(s) 31, 39, 60-62, 65 and 71 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

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### DETAILED ACTION

1. Applicant's response to restriction 11/03/03 is acknowledged. Claims 32-35, 40-59, 63-64, 66-67 and 70 have been canceled. Claims 31, 60-62 have been amended. Claim 71 has been added. Claims are 31, 36-39, 60-62, 65, 68, 69, and 71 are pending in the application.

### *Election*

2. Applicant's election Group I, claims 31, 36-39, 60-62, 65, 68-69 and 71 with respect to SEQID.NO: 2 with traverse, drawn to polypeptide, fusion polypeptide, vaccine and a method of inducing immune response is acknowledged. However, claims 68-69 are drawn to therapeutic composition comprising an antibody and should have been in Group III along with the claims 63-64, drawn to an antibody. The examiner regrets the oversight made in the Restriction requirement on 9/23/03 and any inconvenience caused by this. Therefore, claims 68-69 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention i.e., antibody.

The traversal is on the ground(s) that SEQ.ID.NO: 2, 4 or 6 are similar, share a significant structural element and are isolated from strain *Neisseria meningitidis*.

Applicant also brings examiner attention to MPEP1850, D.

As applicant states group I, i.e., polypeptides SEQ.ID.NO: 2, 4 or 6 are linked by the common generic special technical feature involving an isolated polypeptide comprising SEQ.ID.NO: 2, 4, or 6 because the polypeptides are presented as a Markush group, represent chemical alternatives that are similar nature and presented as % pair wise identities in Table 2, page 51. Although the applicant's above concept may link the three SEQ.ID.NO: 2, 4 or 6, such concept does not constitute a special technical feature as defined by PCT Rule 13.2 (37CFR1.475(a)) because The expression special technical features□ shall mean those technical features that define a contribution which

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each of the claimed inventions, considered as a whole, makes over the prior art.

Specifically Accession number Q9ZHF3 1999 teach this concept i.e., an isolated polypeptide PilQ protein from strain Neisseria meningitidis comprising an amino acid sequence that matches to SEQ.ID.NO: 2, (see attached alignment of SEQ.ID.NO: 2 with, Q9ZHF3 1999 and is 80% identical), therefore it does not constitute a special technical feature by definition. Therefore, lack of unity is present. This is not found persuasive because the examiner believes that the application has been filed under 35 U.S.C. 371, Lack of Unity practice is being followed. The requirement is still deemed proper. Therefore, claims 31, 38, 39, 60-62, 65 and 71 with respect to SEQID.NO: 2 are under examination.

3. Therefore, claims 36-37, drawn to SEQ.ID.NO: 4 or 6 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected sequence. Applicant is advised to restrict the claims to recite only SEQ.ID.NO: 2 since this is an elected invention.

#### ***Priority***

4. This application is a national stage entry of ***PCT/EP99/03603*** International Filing Date: 05/26/1999, which claims priority to foreign application UNITED KINGDOM 9811260.0 05/26/1998 is acknowledged. The examiner has reviewed Foreign applications, Foreign application UNITED KINGDOM 9811260.0 05/26/1998 and find no support for the claimed subject matter, an isolated polypeptide comprising SEQ.ID.NO: 2 (769 amino acids) Accordingly, the subject matter defined in the elected claims, drawn to SEQ ID NO: 2 have an effective filing date of 05/26/1999, that of the **PCT/EP99/03603** because an isolated polypeptide comprising an amino acid sequence, SEQ ID NO: 2 (containing 769 amino acids) is first disclosed in this application.

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***Claim Rejections - 35 USC 112, second paragraph***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

6. Claims 31, 39, 60-62, 65 and 71 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 31 is rejected as being vague in reciting polypeptide comprising SEQ.ID.NO: 2. It is vague because polypeptide comprises an amino acid sequence and is represented by a sequence identification number such as SEQ.ID.NO: 2.

Claim 62 is rejected for the recitation of "one other N.meningitidis antigen". It is difficult to understand the metes and bounds of one other antigen as written because claim does not recite the source of the polypeptide.

***Claim Rejections - 35 USC 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

((b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 31, 39, 60-62 and 65 are rejected under 35 U.S.C. 102(b) as being anticipated by Martin et al 1997 (J.Ex.Med. Volume 185, Number 7, April 7, 1997 1173-1184).

Claims are directed to an isolated polypeptide or immunogenic composition, fusion protein comprising SEQ.ID.NO: 2. Claims are also drawn to a method of inducing an immune response comprising administration of said polypeptide.

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Martin et al disclose an isolated polypeptide, outer membrane polypeptide from whole cell lysate of OM preparations from various clinical isolates including nine meningococcal strains two of serogroup A (604A and Z4063), one of serogroup B (608B [B: 2a:P1.2: L3]), two of serogroup C (2241C and 59C), one of serogroup 29-E, one of serogroup W-135, one of serogroup Y (SLATY) and one of serogroup Z (SLATZ) (page 1174, under materials and method, antigens). Monoclonal antibodies were produced by immunizing mice with OM preparation indicating that the disclosed isolated polypeptide are immunogenic and thus read on claim 43. Applicant's use of the open-ended term "comprising " in the claims fails to exclude unrecited steps or ingredients and leaves the claims open for inclusion of unspecified ingredients, even in major amounts. Whole cell lysates prepared in buffer (pharmaceutical carrier) from N.meningitidis inherently comprise SEQ.ID.NO: 2 and several N.meningitidis antigens in the form of fusion proteins. See *In re Horvitz*, 168 F 2d 522, 78 U.S.P.Q. 79 (C.C.P.A. 1948) and *Ex parte Davis et al.*, 80 U.S.P.Q. 448 (PTO d. App. 1948). In the absence of evidence to the contrary the claimed isolated polypeptide-comprising SEQ.ID.NO: 2 is inherent in the preparations of the disclosed prior art polypeptide. Since the Office does not have the facilities for examining and comparing applicants' claimed isolated polypeptide comprising SEQ.ID.NO: 2, with the polypeptide of prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art. See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald et al.*, 205 USPQ 594.

9. Claims 31 and 71 are rejected under 35 U.S.C. 102(b) as being anticipated by Tonjum et al 1998 Accession number: Q9ZHF3.

Claims are directed to an isolated polypeptide comprising SEQ.ID.NO: 2, said polypeptide is a recombinant polypeptide.

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Tonjum et al 1998 et al disclose an isolated recombinant polypeptide comprising PilQ protein that is 80% identical to the claimed polypeptide (see sequence alignment). Thus the prior art anticipated the claimed invention.

10. Claims 31 and 71 are rejected under 35 U.S.C. 102(b) as being anticipated by Drake et al 1995 (Accession number: Q50972).

Claims are discussed supra.

Drake et al 1998 disclose an isolated recombinant polypeptide comprising PilQ protein that is 78% identical to the claimed polypeptide (see sequence alignment). Thus the prior art anticipated the claimed invention.

#### **Status of Claims**

11. Claim 38 is free of prior art and appears to be allowable.

Claims 31, 39, 60-62, 65 and 71 are rejected.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Padma Baskar whose telephone number is (703) 308-8886. The examiner can normally be reached on Monday through Friday from 6:30 AM to 4 PM EST

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Padma Baskar Ph.D.

1/19/04

  
LYNETTE R. F. SMITH  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER